

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	David E. Francischelli et al.	Examiner:	Peter J. Vrettakos
Serial No.:	10/792,178	Group Art Unit:	3739
Filed:	March 3, 2004	Docket No.:	M190.253.101/P-8575.06
Title:	VIBRATION SENSITIVE ABLATION DEVICE AND METHOD		

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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This pre-appeal memorandum is presented in support of the Notice of Appeal filed herewith and in response to the Office Action mailed on January 9, 2008. Claims 25-33 and 62-79 are pending in the application. Claims 62-79 were withdrawn from consideration. The remaining claims, i.e., claims 25-33, were rejected and are the subject of this pre-appeal. Specifically, claims 25, 26 and 28-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Nardella US Patent No. 5,733,281; and claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nardella US Patent No. 5,733,281 in view of Nardella US Patent No. 5,334,193.

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**Claim Rejections under 35 U.S.C. § 102**

Claims 25, 26 and 28-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Nardella US Patent No. 5,733,281. Claim 25 is an independent claim, and claims 26 and 28-33 depend from claim 25. Claim 25 includes the features of “sensing with a sensor positioned adjacent the electrode the vibration of the organic tissue being ablated, where the vibration is self-generated in the organic tissue in response to the ablation.” Applicants respectfully submit that these features are neither taught nor made obvious in Nardella ‘281 and the prior art of record.

Nardella ‘281 teaches an ablation tool with an ultrasonic feature. The ablation tool sends out an acoustic signal and detects the reflected signal off of the surrounding tissue to determine the energy effects of the surrounding tissue. The feedback system adjusts the energy to the ablation tool based on this determination. Specifically, the Nardella ‘281 specification set out at column 8, lines 38-48, “In operation, the pulse generator 150 emits an electrical pulse along conductor 152 to the transducer 20. The transducer, in response, resonates and emits ultrasonic energy having a selected frequency. . . . The ultrasonic energy is reflected partly by the tissue and partly by the surrounding gas, e.g., steam, that is present at the surgical site. The reflected ultrasound energy is received by the transducer, which then produces electrical signal corresponding to the intensity of the reflected ultrasonic energy.”

Nardella ‘281 does not teach the features of amended claim 25. In the amended features, “the vibration of the organic tissue being ablated . . . is self-generated in the organic tissue in response to the ablation.” There is no corresponding feature in Nardella ‘281 because the measured “vibration” in the prior art is reflected from an ultrasonic signal transmitted with a transducer and not “self-generated in the organic tissue” as set forth in the claim. As described throughout the specification, the organic tissue begins to vibrate in response to the ablation. This is a different vibration than that of reflected ultrasound that is generated with the transducer.

In response to the questions posed in the Office Action, Nardella ‘281 teaches a device that detects nothing more than reflected ultrasonic signal. Regardless of whether the ultrasonic signal is reflected off of tissue, steam, or otherwise, the signal that is received is a reflected version of the signal transmitted. On the other hand, the claims set forth a feature

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that senses vibrations in organic tissue “where the vibration is self-generated in the organic tissue,” which features is in contrast to signals reflected off of the organic tissue. The Office Action, page 4, sets out “Nardella’s transducers emit a pulse and the tissue reflects that pulse, which is sensed.” Applicants agree with this statement. The Office Action continues with, “Self-generated vibrations due to ablation affect the emitted pulse during the reflection and therefore the vibration feedback system is controlled by self generated vibrations as well as transducer emitted pulses. . . . The waves generated by ablation in Nardella inherently affect the emitted wave from the transducer.” While it is true that the reflected wave is affected by the characteristics of the organic tissue, Nardella does not teach receiving anything but an affected reflected version of the signal transmitted. In the feature set forth in the claims, the sensed signal is not a reflected signal, but a self-generated signal.

The difference between Nardella and the present claims can be generally illustrated by comparing, at a high level of abstraction, the difference between radar and two remote ham radio operators having a conversation. The radar in this illustration is similar in some abstraction to the teaching of Nardella. When a radar signal is sent out, it is affected and reflected by a target, and received by a transmitter. Contrast this with two ham radio operators having a conversation. A first operator sends out a first communication signal to a second ham radio operator. The second radio operator sends a second communication signal in response to the first signal back to the first operator, but the second signal is still self-generated by the second operator rather than a reflected version of the first signal. Taking this illustration further, a radar aimed at the second operator would detect the second operator in the reflected wave, but it would not receive the self-generated second communication signal from the second operator.

In addition, the teachings of prior art do not make obvious the newly claimed features of claim 25. There is no recognition in the prior art of the claimed “self-generated [vibration] in the organic tissue in response to the ablation” that can be detected to predict a steam pop as set forth throughout the specification. In all instances, the initial signal in Nardella ‘281 is generated from the device transducer and the return signal from the organic tissue is a reflected signal off of the tissue. Nardella does not discuss and the prior art does not recognize tissue characteristics needed to be detected to predict a steam pop. Nardella does

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not recognize the natural and self-generated vibration in the organic tissue as a result of the ablation and therefore cannot make obvious a modification that does not rely on reflected ultrasound.

Accordingly, Applicants respectfully submit that claim 25 is patentably distinguishable from the prior art of record and request removal of the rejection. Further, claims 26 and 28-33, by virtue of their dependency are patentably distinguishable over the prior art of record. Applicants respectfully request removal of the rejection based on 35 U.S.C. 102.

**Claim Rejections under 35 U.S.C. §103**

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nardella US Patent No. 5,733,281 in view of Nardella US Patent No. 5,334,193. Applicants respectfully submits that claim 27 is patentably distinguishable from the prior art of record. Claim 27 depends on claim 25, which was shown to be patentable over Nardella '281 above. Nardella '193 does not teach the amended features of claim 25 of "the vibration of the organic tissue being ablated . . . is self-generated in the organic tissue in response to the ablation." There is no corresponding feature in Nardella '193 and, as discussed above, there is no corresponding feature in Nardella '281. Because these features are not taught or made obvious in each of the references separately, they cannot be found in any proposed combination of the references. Accordingly, Applicants submit that claim 27 is patentably distinguishable from the prior art combination and respectfully request removal of the rejection based on 35 U.S.C. 103.

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**CONCLUSION**

In view of the above, Applicant respectfully submits that pending claims 25-33 are all in a condition for allowance and requests reconsideration of the application and allowance of all pending claims.

Any inquiry regarding this Request should be directed to Rudolph P. Hofmann at Telephone No. (612) 573-2010, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

**Dicke, Billig & Czaja**  
Fifth Street Towers, Suite 2250  
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Respectfully submitted,

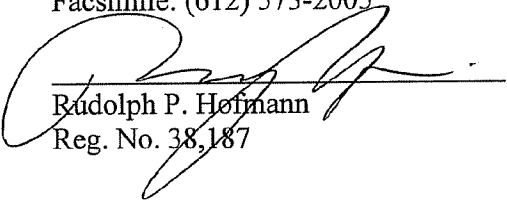
David E. Francischelli et al.,

By their attorneys,

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